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(54) Guide wire for catheters.

(57) A guide wire (11) comprising an elongate flexible cylindrical element (12) formed of metallic material having high torsional capability (e.g. stainless steel) and having a proximal portion having a diameter ranging from .008 to .02 inch (0.2 1 0.51 mm) and a distal portion having a diameter of less than .007 inch (0.18 mm). It also comprises a first coil (13) formed of metallic material (e.g. stainless steel) and secured to the distal portion and a second coil (16) formed of a material which is different from the material of which the first coil (13) is formed and which is substantially radiopaque (e.g. a platinum alloy) secured to the distal extremity of the first coil (13). In addition, it comprises a tip (19) having a rounded conformation secured to the distal extremity of the second coil (16).

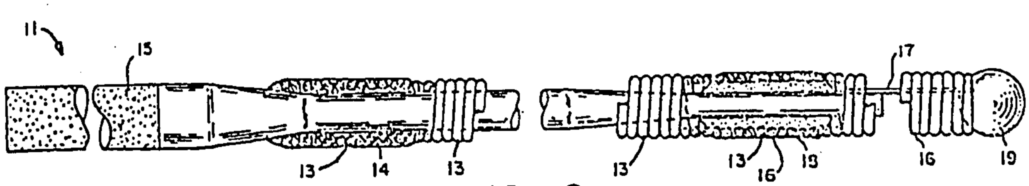

FIG.—2

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GUIDE WIRE FOR CATHETERS

This invention relates to guide devices or "wires" for use in introducing catheters into vascular systems and more particularly to cardiovascular systems in humans.

Guide wires heretofore have been provided to facilitate insertion of catheters into cardiovascular systems. It has been found that with such guide wires it has been difficult to introduce them into very small vessels and particularly into partially occluded segments of such vessels. There is therefore a need for an improved guide wire which can be successfully introduced into small vessels in the cardiovascular system.

Thus, it would be desirable to provide a guide wire for catheters which can be introduced into small vessels in vascular systems and particularly cardiovascular systems in humans and which has high torque capabilities.

It would also be desirable to provide a guide

wire of the above character which has a very floppy distal end.

According to the present invention there is provided a guide device comprising an elongate flexible cylindrical element formed of metallic material having high torsional capability and having a proximal portion having a diameter ranging from .008 to .02 inch (0.2 - 0.51 mm) and a distal portion having a diameter of less than .007 inch (0.18 mm), a first coil formed of metallic material and secured to said distal portion and a second coil formed of a material which is different from the material of which the first named coil is formed and which is substantially radiopaque secured to the distal extremity of the first coil and means having a rounded conformation secured to the distal extremity of the second coil.

The present invention is further described by way of example only with reference to the accompanying drawings, in which:

Figure 1 is a side elevational view of a core wire used in connection with construction of a guide device incorporating the present invention;

Figure 2 is a side elevational view partially in cross section of a guide device incorporating the present invention and which is provided with a floppy distal end; and

Figure 3 is a side elevational view partially in cross section of another embodiment of a guide device incorporating the present invention with a less floppy distal end.

The guide device or "wire" 11 incorporating the invention shown in Figures 1 and 2 consists of a flexible elongate cylindrical element 12 formed of a suitable metallic material having high torsional strength, preferably stainless steel. It should be appreciated that if desired other materials can be utilized than stainless steel, for example certain carbon steel could be used as well as titanium or beryllium copper. The elongate cylindrical element can be in the form of a wire-like hollow cylindrical element or in the form of a wire-like cylindrical solid core.

The wire which is utilized for forming the elongate cylindrical element 12 can be formed in a suitable manner as, for example from No. 304 stainless steel including 20% chromium and 10% nickel and having a minimum of 240 ksi tensile strength. It can be work-hardened by drawing .15 inch (3.8 mm) stainless steel wire material down to .016 inch (0.41 mm) material. The wire can then be straightened and cut to the desired lengths. Thereafter, it can be annealed after which it can be centerless ground to provide the flexible elongate element shown in

Figure 1.

As shown in particular in Figure 1, the flexible elongate cylindrical element 12 is provided with a cylindrical portion 12a having a suitable diameter such as from .008 to .02 inch (0.2 - 0.51 mm) and preferably a diameter of approximately .016 inch (0.41 mm). It is provided with a tapered portion 12b which adjoins one extremity of the cylindrical portion 12a which adjoins another cylindrical portion 12c having a suitable dimension such as .005 to .01 inch (0.13 - 0.25 mm) and preferably a thickness of approximately .008 inch (0.2 mm). Another tapered portion 12d is provided which adjoins the cylindrical portion 12c. Another cylindrical portion 12e adjoins the tapered portion 12d. The cylindrical portion 12e has a suitable dimension less than .007 inch (0.18 mm) such as .003 inch ± .0005 inch (0.076 mm ± 0.013 mm).

The overall flexible elongate element can have a suitable length of a range from 150 to 250 centimeters but preferably has a length of approximately 175 centimeters. Cylindrical portion 12e can have a length ranging from 2 to 6 centimeters and preferably has a length of approximately 4 centimeters. Portion 12c can have a length ranging from 25 to 30 centimeters and preferably has a length of approximately 26.5

centimeters. The tapered portion 12d can have a length of approximately one-half of a centimeter whereas the tapered portion 12b can have a length of approximately 1 centimeter.

The proximal end of the elongate flexible element 12 is coated with a suitable material so as to facilitate movement of the guide wire hereinafter described through the coronary vessels. For example a substantial portion of the cylindrical portion 12a can be coated with a Teflon (Registered Trade Mark) coating 15 to suitable thickness, for example a thickness of .001 inch (0.025 mm).

An elongate coil 13 of a suitable material such as stainless steel is secured to the distal extremity of the cylindrical element 12 by suitable means such as the use of solder 14 as shown particularly in Figure 2. As shown, the coil 13 extends over the cylindrical portion 12c and the solder joint 14 between the flexible element 12 and the elongate coil 13 is formed in the vicinity of the tapered portion 12b.

The coil 13 is formed from stainless steel wire having a diameter of approximately .003 inch (0.076 mm) and is wound so that the coil has an outer diameter of approximately .017 inch (0.43 mm). The coil 13 is wound in such a manner so that the coils are tightly packed or in other words "bottomed out". The solder 14 is applied

to the coil in such amounts that it fills interstices between the coil but does not significantly increase the outer diameter of the coil. The coil 13 extends towards the distal end of the elongate element 12 into a region which is adjacent the cylindrical portion 12e.

Another elongate coil 16 formed of a material which is substantially opaque to X-rays is provided. It should generally be formed of a material which has a density of at least 13 gm/cm^3. Suitable materials meeting this requirement include gold, tantalum, tungsten, platinum, iridium, rhenium and alloys of these materials. The wire which is utilized for the elongate coil 16 is formed of a platinum alloy and has suitable dimensions but preferably has dimensions which are substantially identical to the dimensions of the stainless steel coil 13. For that reason the wire would have a diameter of .003 inch (0.076 mm) and would be wound so that the coil would have an outside diameter of approximately .017 inch (0.43 mm). One end of the elongate platinum coil 16 is threaded or screwed into the distal extremity of the elongate stainless steel coil 13 as shown particularly in Figure 2 in such a manner that alternate turns of the coil 16 are disposed between alternate turns of the coil 13. This screwed connection is represented by the

cross-sectional lines in Figure 2, where the cross-sectional lines for the stainless steel extend in one direction and the cross-sectional lines for the platinum extend in a direction which is displaced by 90°. In order to provide additional flexibility in the platinum coil 16, the turns of the coil rather than being tightly packed or "bottomed out" are spaced apart a suitable distance as for example .005 to .0015 inch (0.13 - 0.038 mm). Alternatively, the two coils 13 and 16 can be butted together.

A safety ribbon 17 formed of a suitable material such as tungsten of suitable dimensions such as a width of .003 inch (0.076 mm) and a thickness of .001 inch (0.025 mm) extends from the extremity of the elongate cylindrical element 12 to the outermost or distal extremity of the coil 16. The proximal extremity of the safety ribbon 17 and the two ends of the coils 13 and 16 which have been screwed or butted together are joined into a unitary assembly with the elongate element 12 by suitable means such as brazing 18. As with respect to the solder joint 14, the brazing joint 18 is formed in such a manner so that the material fills the interstices between the coils 16. The brazing 18 secures the proximal extremity of the safety wire 17 to the cylindrical portion 12e of the elongate element 12.

As shown in Figure 2, the coil 16 extends a suitable distance beyond the distal extremity of the element 12, as for example a length of 1 to 2 centimeters from the end and preferably 1.5 centimeters from the end. The distal extremity of the coil 16 is provided with suitable means for rounding off the extremity as well as securing the distal extremity of the safety wire 17 and consists of a ball or plug 19 formed of a suitable

material such as gold which is bonded onto the distal end of platinum coil 16 and the distal extremity of the ribbon 17.

The solder and brazing materials utilized in connection with the manufacture of the guide wire shown in Figures 1 and 2 may be of conventional types. For example, the solder can be a conventional copper, silver alloy or a ton silver alloy whereas the brazing material can be an alloy of silver, copper, tin and nickel.

The guide wire hereinbefore described can be characterized as being a floppy wire since it is provided with a very flexible distal extremity which can be utilized for exploring vessels in the caridovascular system to facilitate the introduction of balloon-type catheters in a manner well known to those skilled in the art. The conformation of the guide wire can readily follow the vessels in the cardiovascular system. The travel can also be observed by the use of a conventional fluoroscope.

Another guide wire incorporating the invention which has slightly less flexibility or floppiness in the guide wire shown in Figures 1 and 2 is shown in Figure 3. The guide wire 26 shown in Figure 3 consists of an elongate cylindrical element 12 of the type hereinbefore described in conjunction with Figures 1 and 2. Similarly, a coil 13 formed of stainless steel in the manner hereinbefore described in the embodiment shown in Figures 1 and 2 is utilized and is bonded to the flexible elongate element 12 by the solder 14 hereinbefore described. A coil 27 formed of platinum in the same manner as the coil 16 was formed is provided, however, the coil 27 has a lesser length than the coil

16 so that it only extends to the distal end of the elongate flexible element 12. The coil 27 is again threaded into the distal extremity of the coil 13 and is bonded to the elongate element 12 by brazing 18. Since coil 27 does not extend beyond the end of the flexible elongate element 12, it is not necessary to provide the safety wire 17 which is provided in the embodiment shown in Figures 1 and 2. A plug or ball 28 formed of a suitable material such as gold is formed on the distal extremity of the coil 17 and is also bonded to the distal extremity of the flexible elongate element 12. As in the previous embodiment, to provide additional flexibility the turns of the coil 27 on the outer extremity can be spaced apart as for example a distance of .0005 to .0015 inch (0.13 - 0.038mm).

From the foregoing it can be seen that there has been provided guide wires with varying degrees of flexibility so that guide wires of different capabilities can be provided to negotiate the various types of vessels which are encountered in cardiovascular systems and particularly vessels which are partially occluded. Guide wires of this type facilitate negotiating such occlusions to facilitate introduction of balloon catheters in a manner well known to those skilled in the art. The coils provided inhibit permanent deformation of the guide wire.

CLAIMS:

1. A guide device comprising an elongate flexible cylindrical element formed of metallic material having high torsional capability and having a proximal portion having a diameter ranging from .008 to .02 inch (0.2 - 0.51 mm) and a distal portion having a diameter of less than .007 inch (0.18 mm), a first coil formed of metallic material and secured to said distal portion and a second coil formed of a material which is different from the material of which the first named coil is formed and which is substantially radiopaque secured to the distal extremity of the first coil and means having a rounded conformation secured to the distal extremity of the second coil.

2. A guide device as claimed in claim 1 wherein the outer extremity of the coil extends beyond the distal extremity of the flexible elongate cylindrical element together with a safety wire secured to the outer extremity of the second coil and to the flexible elongate element.

3. A guide device as claimed in claim 1 wherein said means having a rounded conformation is bonded to

the distal extremity of the flexible elongate cylindrical element.

4. A guide device as claimed in any one of the preceding claims wherein said first and second coils are screwed together so that at least a portion of each coil has individual turns which are disposed between individual turns of the other coil.

5. A guide device as claimed in claim 4 wherein the portions which are screwed together are brazed together and are brazed to the flexible elongate element.

6. A guide device as claimed in claim 1 wherein the second coil extends beyond the distal extremity of the flexible elongate element together with a safety wire and wherein one end of the safety wire is brazed to the flexible elongate element and the other end of the safety wire is bonded to the means having a rounded conformation.

7. A guide device as claimed in any one of the preceding claims wherein said first coil is formed of stainless steel and wherein said second coil is formed of a platinum alloy.

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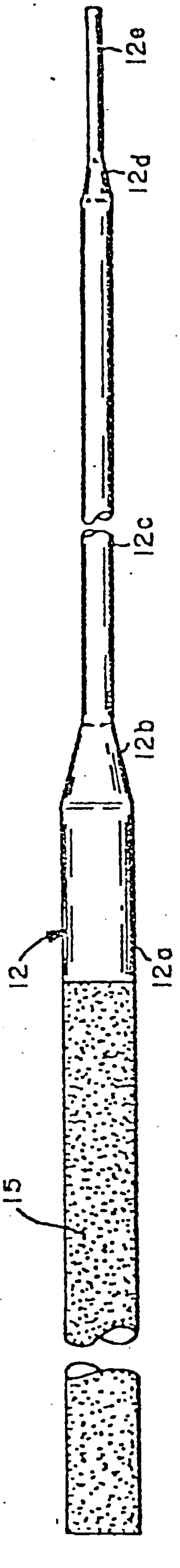

FIG.—1

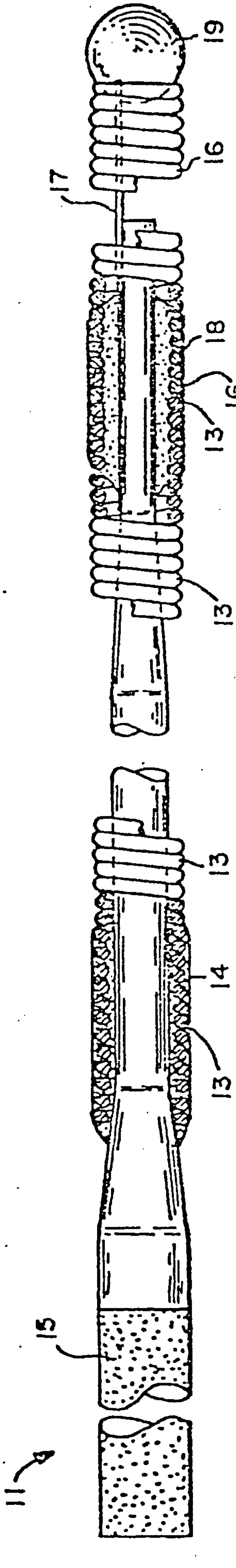

FIG.—2

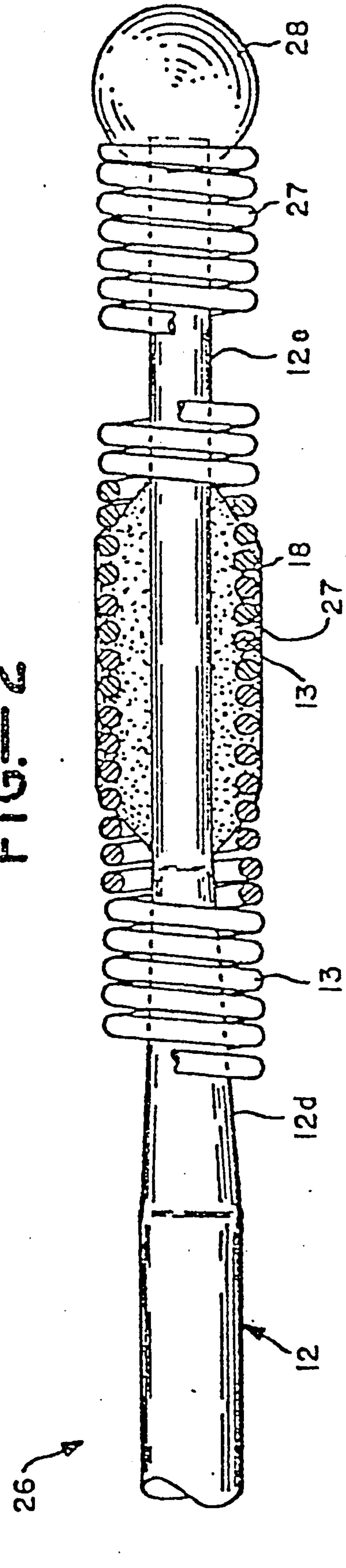

FIG.—3